IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,)
Plaintiff,))
V.) Case No. 1:10-CV-1376-TWP-DKL
TEVA PARENTERAL MEDICINES, INC.,)
APP PHARMACEUTICALS, LLC,)
PLIVA HRVATSKA D.O.O.,)
TEVA PHARMACEUTICALS USA, INC.,)
and BARR LABORATORIES, INC.,)
,)
Defendants.)

JOINT STIPULATION REGARDING ISSUES AT TRIAL

Plaintiff Eli Lilly and Company ("Lilly") and Defendants Teva Parenteral Medicines, Inc. ("Teva Parenteral"), Teva Pharmaceuticals USA, Inc. (collectively with Teva Parenteral, "Teva"), and APP Pharmaceuticals, LLC ("APP") (collectively "Defendants") jointly submit the following stipulations for the Court's approval:

Infringement:

- 1. Teva is seeking FDA approval to market the pemetrexed products identified in Teva's Abbreviated New Drug Application ("ANDA") Nos. 90-352 and 90-674. APP is seeking FDA approval to market the pemetrexed products identified in APP's ANDA No. 90-384. Collectively these products are called in this document the "ANDA Products."
- 2. Lilly stipulates that it is only asserting against Defendants infringement of claims 9, 10, 12, 14, 15, 18, 19, and 21 of U.S. Patent No. 7,772,209 (the "'209 patent") with respect to the ANDA Products.
- 3. Each Defendant stipulates that under the Court's claim construction in the above captioned litigation and under the current law of infringement, including as set forth in *Akamai*

Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301 (Fed. Cir. 2012) (en banc) ("*Akamai*"), the sale of its ANDA products, in accordance with the proposed labeling for each of those respective ANDA products, would induce the infringement of claims 9, 10, 12, 14, 15, 18, 19, and 21 of the '209 patent, to the extent those claims are found valid and enforceable.

4. However, the Federal Circuit's decision in *Akamai* addresses the standard for inducement of infringement and is currently the subject of a pending petition to the United States Supreme Court for a writ of certiorari. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, No. 12-786 (S. Ct., filed Dec. 28, 2012). As a result, the parties agree that, in the event that the Supreme Court grants the petition for certiorari and either (1) reverses or vacates the Federal Circuit's decision in *Akamai* or (2) affirms the Federal Circuit's decision in *Akamai* but applies a materially different standard in deciding the issue of induced infringement, Defendants may bring the Supreme Court's ruling to this Court's attention within 14 days of its issuance and the parties may then litigate infringement, inducement of infringement, and contributory infringement. The parties anticipate that this stipulation will eliminate the need for unnecessary presentation of evidence at trial, and further stipulate that if an evidentiary presentation is needed after the Supreme Court's decision, the parties will make that presentation with no more than one live witness per side.

Inventorship and 35 U.S.C. § 102(f) Derivation:

5. Defendants stipulate that they are not asserting improper inventorship as a defense at trial or that any prior art against the '209 patent exists under 35 U.S.C. § 102(f), with one contingency: that in the event their request for discovery under the Hague convention is granted such that they are able to take Dr. Hilary Calvert's deposition before trial, upon notice to Plaintiff not later than 2 days after the deposition, Defendants may give notice that they intend to use that

deposition in support of an argument that Dr. Calvert, Dr. Robert Allen, Dr. Paolo Paoletti, or Dr. James Rusthoven should have been named as an inventor on the '209 patent and may raise at trial a defense that any of those four individuals should have been named as an inventor on that patent. With those same time constraints, Defendants may also give notice that they intend to use that deposition in support of an argument that Dr. Calvert's and/or Dr. Allen's communications to Lilly or the named inventor of the '209 patent are prior art under 35 U.S.C. § 102(f). In such a circumstance, the parties shall be permitted to (1) file supplemental pre-trial briefs of no more than 7 pages to address the inventorship defense and/or the 35 U.S.C. § 102(f) issue(s); (2) amend their exhibit lists to include additional exhibits (if any) to address the inventorship defense and/or the 35 U.S.C. § 102(f) issue(s); (3) amend their witness list to include additional witnesses (if any) to address the inventorship defense and/or the 35 U.S.C. § 102(f) issue(s); and (4) amend their deposition designations to designate additional testimony to address the inventorship defense and/or the 35 U.S.C. § 102(f) issue(s).

6. Not later than 2 days after Dr. Calvert's deposition, any party must give notice if they intend to use portions of the deposition for any purpose relevant to the case.

/s/ Megan A. Hughes

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2013, I caused a copy of the foregoing Joint Stipulation Regarding Issues at Trial to be served electronically via operation of the Court's CM/ECF system upon the following:

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> /s/ Megan A. Hughes Megan A. Hughes